

§493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory's participation in proficiency testing is unsuccessful, CMS may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§493.1806 and 493.1807.

§493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by CMS for any information or work on materials that CMS concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS;

(5) Refused a reasonable request by CMS or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

(This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, CMS suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation—*(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, CMS does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in §493.1844) that upholds suspension or limitation.

(2) *Exceptions.* CMS may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for CMS or a CMS agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) CMS may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* CMS notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

§493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) CMS always cancels a laboratory's approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory's CLIA certificate.

(2) CMS may cancel the laboratory's approval under any of the following circumstances:

- (i) The laboratory is out of compliance with a condition level requirement.
- (ii) The laboratory fails to submit a plan of correction satisfactory to CMS.
- (iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, CMS gives the laboratory—

- (1) Written notice of the rationale for, effective date, and effect of, cancellation;
- (2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in § 493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§ 493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.

(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.

(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.

(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently,

the laboratory has a right to only one hearing on all matters at issue.

(b) *Actions that are initial determinations.* The following actions are initial determinations and therefore are subject to appeal in accordance with this section:

- (1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by CMS because of noncompliance with CLIA requirements.
- (2) The denial of a CLIA certificate.
- (3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).
- (4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

(c) *Actions that are not initial determinations.* Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:

- (1) The finding that a laboratory accredited by a CMS-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, and Q of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.
- (2) The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.
- (3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.
- (4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.
- (5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.
- (6) The determination that a laboratory's deficiencies pose immediate jeopardy.